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August 13, 2004

CERTIFICATE OF MAILING
37 C.F.R 1.8

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August 13, 2004 — Date

Gina N. Shishima

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/747,798 entitled "p53 TREATMENT OF PAPILLOMAVIRUS AND CARCINOGEN-TRANSFORMED CELLS IN HYPERPLASTIC LESIONS" – George H. Yoo*
Our reference: INRP:104US

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A7, B1-B2, and C1-C95.

No fees are believed to be due in connection with the filing of this Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:104US.

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Respectfully submitted,

Gina N. Shishima
Reg. No. 45,104

GNS/kmv
Encl.: as noted

25443408.1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
George H. Yoo

Serial No.: 10/747,798

Filed: December 29, 2003

For: p53 TREATMENT OF PAPILLOMAVIRUS AND CARCINOGEN-TRANSFORMED CELLS IN HYPERPLASTIC LESIONS

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: INRP:104US

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Gina N. Shishima

INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

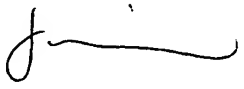
an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:104US.

Applicant respectfully requests that the listed documents be made of record in the present case.

The reference identified as C95 is believed to be a copy of a presentation made at the Recombinant DNA Advisory Committee (RAC) meeting on March 8, 2001, but Applicant's representative is not certain of this. Furthermore, the documents identified as C23 and C24, which appear to correspond to this presentation, are believed to have been available on the RAC website at least as early as March 2001, but this is not certain as well.

Respectfully submitted,



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List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT	Applicant George H. Yoo	
(Use several sheets if necessary)	Filing Date: December 29, 2003	Group: Unknown

U.S. Patent Documents	Foreign Patent Documents	Other Art
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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,747,469	5/05/98	Roth *et al.*	514	44	4/25/94
	A2	6,017,524	1/25/00	Roth *et al.*	424	93.2	10/13/92
	A3	6,410,010	6/25/02	Zhang and Roth	424	93.2	10/29/93
	A4	6,511,847	1/28/03	Zhang and Roth	435	320.1	9/21/00
	A5	2002/0187105	12/12/02	Zou and Perez-Soler	424	45	2/01/02
	A6	2002/0051767	6/20/02	Clayman	514	44	10/01/01
	A7	2002/0077313	5/02/02	Chiang and Chang	424	93.21	9/13/95

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 95/12660	5/11/95	PCT			English
	B2	WO 95/28948	11/02/95	PCT			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C1	"Recombinant DNA Advisory Committee: Recombinant DNA and Gene Transfer," http://www4.od.nih.gov/oba/rac/aboutrdagt.htm.
	C2	"Human genetics in the public interest," Center for Genetics and Society, http://www.genetics-and-society.org/policies/us/agencies.html.
	C3	Baker *et al.*, "Suppression of human colorectal carcinoma cell growth by wild-type p53," *Science*, 249:912-915, 1990.
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	C6	Berges *et al.*, "Cell proliferation, DNA repair, and p53 function are not required for programmed cell death of prostatic glandular cells induced by androgen ablation," *Proc. Natl. Acad. Sci., USA*, 8910-8914, 1993.
	C7	Boyle *et al.*, "The incidence of p53 mutation increases with progression of head and neck cancer," *Cancer Res.*, 53:4477-4480, 1993.
	C8	Bramwell, "The role of chemotherapy in multimodality therapy," *Canadian J. of Surgery*, 31(6):390-396, 1988.
	C9	Brennan *et al.*, "Molecular assessment of histopathological staging in squamous-cell carcinoma of the head and neck," *NEJM*, 332(7):429-435, 1995.
	C10	Cai *et al.*, "Stable expression of the wild-type p53 gene in human lung cancer cells after retrovirus-mediated gene transfer," *Human Gene Therapy*, 4:617-624, 1993.
	C11	Cajot *et al.*, "Growth suppression mediated by transfection of p53 in Hut292DM human lung cancer cells expressing endogenous wild-type p53 protein," *Cancer Research*, 52(24):6956-6960, 1992.
	C12	Calhoun *et al.*, "Distant metastases from head and neck squamous cell carcinomas," *Laryngoscope*, 104:1199-1205, 1994.
	C13	Casey *et al.*, "Growth suppression of human breast cancer cells by the introduction of a wild-type p53 gene," *Oncogene*, 6:1791-1979, 1991.
	C14	Chen *et al.*, "Genetic mechanisms of tumor suppression by the human p53 gene," *Science*, 250:1576-1580, 1990.
	C15	Chiang *et al.*, "Expression and purification of general transcription factors by flag epitope tagging and peptide elution," *Pept. Res.*, 6(2):62-64, 1993.
	C16	Chung *et al.*, "Discordant p53 gene mutations in primary head and neck cancers and corresponding second primar y cancers of the upper aerodigestive tract," *Cancer Res.*, 53:1676-1683, 1993.
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	C19	Clayman *et al.*, "Adenovirus-mediated wild-type p53 gene transfer as a surgical adjuvant in advanced head and neck cancers," *Clin. Cancer Res.*, 5:1715-1722, 1999.
	C20	Clayman *et al.*, "Comparing the tumor suppressor gene p53 and a cell cycle regulator WAF1/CIP1(p21)," *Arch. Otolaryngol Head Neck Surg.*, 122:489-493, 1996.
	C21	Clayman *et al.*, "In vivo molecular therapy with p53 adenovirus for microscopic residual head and neck squamous carcinoma," *Cancer Res.*, 55(1):1-6, 1995.
	C22	Clayman *et al.*, "Regulation of urokinase-type plasminogen activator expression in squamous-cell carcinoma of the oral cavity," *Int. J. Cancer*, 54:73-80, 1993.
	C23	Clayman, "Clinical protocol for wild type p53 gene induction in premalignancies of squamous epithelium of the oral cavity via an adenoviral vector," Scientific Abstract, sponsored by Introgen, Inc.
	C24	Clayman, "Clinical protocol for wild type p53 gene induction in premalignancies of squamous epithelium of the oral cavity via an adenoviral vector," Non-Technical Abstract, sponsored by Introgen, Inc.
	C25	Couch *et al.*, "Immunization with types 4 and 7 adenovirus by selective infection of the intestinal tract," *Am. Rev. Resp. Dis.*, 88:394-403, 1963.
	C26	Denissenko *et al.*, "Preferential formation of benzo[a]pyrene adducts at lung cancer mutational hotspots in p53," *Science*, 274:430-432, 1996.
	C27	Der and Cooper, "Altered Gene Products Are Associated with Activation of Cellular ras^k Genes in Human Lung and Colon Carcinomas", *Cell*, 32:201-208, 1983.
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	C32	Fearon *et al.*, "Identification of a chromosome 18q gene that is altered in colorectal cancers," *Science*, 247:49, 1990.
	C33	Field *et al.*, "Elevated expression of the c-myc oncoprotein correlates with poor prognosis in head and neck squamous cell carcinoma," *Oncogene*, 4:1463-1468, 1989.
	C34	Field *et al.*, "The role of the p53 tumor suppressor gene in squamous cell carcinoma of the head and neck," *Arch. Otlaryngol. Head and Neck Surg.*, 119:1118-1122, 1993.
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	C36	Fujiwara *et al.*, "Therapeutic effect of a retroviral wild-type p53 expression vector in an orthotopic lung cancer model," *JNCI*, 86:1458-1462, 1994.
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	C38	Ganly and Singh, "Topical ONYX-015 in the treatment of premalignant oral dysplasia: another role for the cold virus?" *J. Clin Oncol.*, 21(24):4476-4478, 2003.
	C39	Gillison *et al.*, "Evidence for a causal association between human papillomavirus and a subset of head and neck cancers," *J. Natl. Cancer Inst.*, 92:709-720, 2000.
	C40	Hamada *et al.*, "Adenovirus-mediated transfer of a wild-type p53 gene and induction of apoptosis," *Cancer Res.*, 56(13):3047-3054, 1996.
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	C42	Hamada *et al.*, "Growth inhibition of human cervical cancer cells with the recombinant adenovirus p53 in vitro," *Gynecol. Oncol.*, 60:373-379, 1996.
	C43	Hollstein *et al.*, "p53 mutations in human cancers," *Science*, 253:49-53, 1991.
	C44	Hopp *et al.*, "A short polypeptide marker sequence useful for recombinant protein identification and purification," *Bio/Technology*, 6:1204-1210, 1988.
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	C46	Huang *et al.*, "Mitomycin C and cisplatin enhanced the antitumor activity of p53-expressing adenovirus in cervical cancer cells," Cancer Investigation, 19(4):360-368, 2001.
	C47	Jackson et al., "Wild type p53 down regulates transcription from different virus cancer/ promoters," *Oncogene*, 8(3):589-597, 1993.
	C48	Kastan *et al.*, "A mammalian cell cycle checkpoint pathway utilizing p53 and GADD45 is defective in ataxia-talangiectasia," *Cell*, 71:587-597, 1992.
	C49	Katayose et al., "Cytotoxic effects of adenovirus-mediated wild-type p53 protein expression in normal and tumor mammary epithelial cells," Clinical Cancer Research, 1:889-897, 1995.
	C50	Koch *et al.*, "p53 mutation and locoregional treatment failure in head and neck squamous cell carcinoma," *J. Natl. Cancer Inst.*, 88:1580-1586, 1996.
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	C54	Maestro *et al.*, "High frequency of p53 gene alterations associated with protein overexpression in human squamous cell carcinoma of the larynx," *Oncogene*, 7:1159-1166, 1992.
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	C56	Mashal *et al.*, "Rearrangement and expression of p53 in the chronic phase and blast crisis of chronic myelogenous leukemia," *Blood*, 75:180-189, 1990.
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	C58	Mitchell *et al.*, "Transgene expression in the rhesus cervix mediated by an adenovirus expressing β-galactosidase," Am. J. Obstet. Gynecol., 174(4):1094-1101, 1996.
	C59	Neilsen and Manaval, "p53 tumor suppressor gene therapy for cancer," *Cancer Gene Therapy*, 5(1):52-63, 1998.

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	C60	Nemunaitis *et al.*, "Three phase III trials of intratumoral injection with a replication-deficient adenovirus carrying the p53 gene (AD5CMV-P53) in patients with recurrent/refractory head and neck cancer," *Proc. An. Soc. Clin. Oncol.*, 18:431a, 1999.
	C61	Nishizaki *et al.*, "Recombinant adenovirus expressing wild-type p53 is antiangiogenic: a proposed mechanism for bystander effect," *Clin. Cancer Res.*, 5:1015-1023, 1999.
	C62	Nylander *et al.*, "p53 expression and cell proliferation in squamous cell carcinomas of the head and neck," *Cancer*, 75:87-93, 1995.
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	C65	Ogiso *et al.*, "Suppression of various human tumor cell lines by a dominant negative H-ras mutant," *Gene Ther.*, 1:403-407, 1994.
	C66	Oren and Levine, "Molecular cloning of a cDNA specific for the murine p53 cellular tumor antigen," *Proc. Natl. Acad. Sci., USA*, 80:56-59, 1983.
	C67	Pavelic *et al.*, "Overexpression of a p52 protein is common in premalignant head and neck lesions," *Anticancer Research*, 14:2259-2266, 1994.
	C68	Perrem *et al.*, ""p53 represses SV40 transcription by preventing formation of transcription complexes," *Oncogene*, 11(7):1299-1307, 1995.
	C69	Ramqvist *et al.*, "Wild-type p53 induces apoptosis in a Burkitt lymphoma (BL) line that carries mutant p53," *Oncogene*, 8:1495-1550, 1993.
	C70	Riccioni *et al.*, "Adenovirus-mediated wild-type p53 overexpression inhibits endothelial cell differentiation in vitro and angiogenesis in vivo," *Gene Ther.*, 5:747-754, 1998.
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	C72	Rudin *et al.*, "An attenuated adenovirus, ONYX-015, as mouthwash therapy for premalignant oral dysplasia," *J. Clin. Oncology*, 21(24):4546-4552, 2003.
	C73	Sacks *et al.*, "Establishment and characterization of two new squamous cell carcinoma cell lines derived from tumors of the head and neck," *Cancer Res.*, 48:2858-2866, 1988.

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	C76	Shaw *et al.*, "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line," *Proc. Natl. Acad. Sci., USA*, 89:4495-4499, 1992.
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	C80	Su *et al.*, "Production of recombinant porcine tumor necrosis factor alpha in a novel E. coli exprssion system," *BioTechniques*, 13(5):756-762, 1992.
	C81	Subler *et al.*, "Inhibition of viral and cellular promoters by human wild-type p53," *J. Virol.*, 66(8):4757-4762, 1992.
	C82	Suzuki, et al., "p53 Mutations in Non-Small Cell Lung Cancer in Japan: Association between Mutations and Smoking1," Cancer Res., 52:734 736, 1992.
	C83	Tabin *et al.*, "Mechanism of activation of a human oncogene," *Nature*, 300(11):143-149, 1982.
	C84	Wang *et al.*, "Apoptosis induced in human osteosarcoma cells is one of the mechanisms for the cytocidal effect of AdCMV-p53," *Cancer Gene Therapy*, 2(1):1-9, 1995.
	C85	Watling *et al.*, "Overexpression of p53 in head and neck cancer," *Head and Neck*, 14(6):437-444, 1992.
	C86	Wijsman *et al.*, "A new method to detect apoptosis in parrifin section: in situ end-labeling of fragmented DNA," *J. Histochem. Cytochem.*, 41:7-12, 1993.
	C87	Wilcock and Lane, "Localization of p53, retinoblastoma, and host replication proteins at sites of viral replication in hepes-infected cells," *Nature*, 349:429-431, 1991.

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	C88	Wills et al., "Development and characterization of recombinant adenoviruses encoding human p53 for gene therapy cancer," Human Gene Therapy, 5:1079-1088, 1994.
	C89	Yamamoto *et al.*, "High incidence of amplification of the epidermal growth factor receptor gene in human squamous carcinoma cell lines," *Cancer Res.*, 46:414-416, 1986.
	C90	Yonish-Rouach *et al.*, "Wild-type p53 induces apoptosis of myeloid leukaemic cells that is inhibited by interleukin-6," *Nature*, 352:345-347, 1991.
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